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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,439

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Gianluca Civenni

I-32642A/FMI

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05/08/2006

EXAMINER

HALVORSON, MARK

NOVARTIS

CORPORATE INTELLECTUAL PROPERTY

ONE HEALTH PLAZA 104/3

EAST HANOVER, NJ 07936-1080

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/528,439	CIVENNI ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1-27 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-10, 17-19, drawn to a method for inhibiting EGF receptor signaling **in vitro**, said method comprising contacting a cell having EGF receptors and Frizzled (Fz) at the cell surface with a Wnt antagonist in a sufficient amount to reduce the EGF receptor and a kit for detecting Erb signaling.

Group 2, claim(s) 1-10, drawn to a method for inhibiting EGF receptor signaling, **in vivo**, said method comprising contacting a cell having EGF receptors and Frizzled (Fz) at the cell surface with a Wnt antagonist in a sufficient amount to reduce the EGF receptor.

Group 3, claims 11- 16 drawn to a method of screening for compounds effective in modulating Wnt-mediated ErbB receptor signaling.

Group 4, claim(s) 20-26 drawn to a method for inhibiting ErbB signaling in a patient, the method comprising administering to a patient a composition comprising a Wnt antagonist in a sufficient amount to reduce the ErbB signaling in a cell of a patient.

Group 5, claim 27 drawn to a method of diagnosing a patient in need of treatment with a Wnt antagonist, said method comprising detecting Erb receptor signaling.

3. An national stage application shall relate to one invention only or to a

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group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group 1 drawn to a method for inhibiting EGF receptor signaling in vitro, said method comprising contacting a cell having EGF receptors and Fz at the cell surface with a Wnt antagonist in a sufficient amount to reduce the EGF receptor and a kit for detecting Erb signaling. All of the other Groups are drawn to additional methods that do not comprise combinations of Groups 1. Therefore, restriction is proper.

SPECIES ELECTION

4. Claims 1-16, 20-27 are drawn to methods using multiple compounds that fails the Harnisch test. Claims 17-19 are drawn to kits comprising different molecules that fail the Harnish test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush

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group share a substantial structural feature disclosed as being essential to that utility.

However, the molecules of each of claims 3-6, 14, 17, 21, 22, and 24 do not share as a whole, a substantial structural feature, one with the other because Wnt antagonists, Wnt1, Wnt5a, sFRP, antibodies to WNT and antibody to Fz are polypeptides with structurally different polypeptide sequences. Further, the methods of ErbB signaling use different reagents with different structures.

Thus each of these claims fail the Harnisch test and they do not meet the requirements to be accorded Markush practice under MPEP 803.02. Applicant must elect not only a single molecule but also a single nucleic acid or polypeptide for examination.

(i). **Group 1** is further subject to election of one of the disclosed species.

Claim 1 is generic to a plurality of Wnt antagonists that have different structures and functions wherein the species are (a) **Wnt1** (b) **Wnt5** (c) **antibody or fragment which specifically binds to Wnt** (d) **antibody or fragment which specifically binds to Fz** or (e) **sFRP**.

(ii) **Group 1** is further subject to election of one of the disclosed species.

Claim 17 is generic to a plurality of compounds and/or cells that have different structures and functions wherein the species are (a) **Wnt and Fz**, (b) **Wnt and Fz and a cell expressing Wnt** (c) **Wnt and Fz and a cell expressing Fz** (d) **Wnt and Fz and a cell expressing Wnt and Fz** or (e) **a cell expressing Wnt and Fz**

(iii). **Group 3** is further subject to election of one of the disclosed species.

Claim 13 is generic to a plurality of methods of detecting ErbB signalling involving different structures and functions wherein the species are (a) **detecting the presence of ERK activity** (b) **detecting the presence of MAPK activity** (c) **detecting the presence of ErbB phosphotyrosine activity** (d) **detecting the**

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presence of cyclin D activity or (e) detecting the presence of a reporter gene product.

(iv). **Group 4** is further subject to election of one of the disclosed species.

Claim 20 is generic to a plurality of Wnt antagonists that have different structures and functions wherein the species are (a) **antibody or fragment which specifically binds to Wnt** or (b) **antibody or fragment which specifically binds to Fz.**

(v). **Group 4** is further subject to election of one of the disclosed species.

Claim 23 is generic to a plurality of types of cancer having different etiologies and treatments wherein the cancers are (a) **breast** or (b) **colon.**

5. Applicant is advised that a reply to this requirement must include an identification of all of the species that are elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD
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571-272-6539


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER